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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/121,239 07/23/98 HARVEY

R GP091-02.UT

021365 HM22/0412  
GEN PROBE INCORPORATED  
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SAN DIEGO CA 92121

EXAMINER

SCHMIDT, M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED:

*10*  
04/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/12/239

Applicant(s)

Harvey et al.

Examiner

Schmidt

Group Art Unit

1635

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 1/27/00.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 9
- ☐ Interview Summary, PTO-413
- Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Saunders et al., for the same reasons of record as argued in the previous Official action on the merits mailed 08/18/99.

Applicant's arguments filed 1/27/00 have been fully considered but they are not persuasive.

Applicant noted on page 6 of the response that claim 19 had been amended. No such amendment was found in the response however. Therefore, the rejection is sustained based on the original claims filed.

Applicants argue on page 7 and 8 of the response that the claimed invention differs from Saunders et al. since applicants claim use of "a non-ionic detergent" and Saunders et al. used Sarcosyl, which is an anionic detergent.

However, in view of the comprising language in the claim as written, the claim also reads on additional steps which may comprise a different detergent known in the art (such as that taught by Saunders et al.). Further, any detergent will cause some viscosity since absent evidence to the contrary, any lysing of a cell with release both types of nucleic acids, DNA and RNA.

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*Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eskola et al., Kacian et al. (U.S. Patent 5,399,491), and Saunders et al. in view of Rowley et al., Morris et al., von Lindern et al., Goddard et al., Gruenwald et al., and Ohki et al. for the same reasons of record as argued in the previous Official action on the merits mailed 08/18/99.

Applicant's arguments filed 1/27/00 have been fully considered but they are not persuasive.

Applicant amended claims 1-6, 9-10, 16 and 18 to correct certain language issues. The limitation "isothermal" was also added to some of the claims. Applicant teaches in the specification that this limitation is met by the methods taught by Kacian et al. (U.S. Patent 5,399,491).

Applicant argues that Eskola et al. do not teach the method claimed since "detection, as taught by Eskola et al. requires one probe that binds the amplified sequence to a solid surface... and one labeled probe that is used to detect the bound complex. Both probes of Eskola et al. must bind for the amplified sequence to be detected. In contrast, Applicants' "hybridizing" step, uses a probe that binds to the first or the second probe binding site. Thus Eskola et al. do not suggest Applicant's methods." In response, the two probes taught by Eskola et al. for amplification of the nucleic acid target read on the limitations of the claims for "a first probe binding site....and a second probe binding site" and therefore read on the claims as written.

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Although the claims as amended claim the detection probe binding to "the first or the second probe binding site, thereby forming a probe:target hybrid", it would have been within the ordinary skill of the artisan at the time the invention was made to detect the claimed nucleic acid using at least one of the probes taught by Eskola et al. since such methods of detection were known to one of ordinary skill in the art.

Applicant further argues in reference to the Kacian et al. reference that the "disclosure regarding primer optimization does not suggest the presently claimed methods of amplifying and detecting amplified sequences that contain a splice junction." However, the claimed invention as broadly claimed is drawn to methods of detecting a fusion nucleic acid sequence in a sample. Kacian et al. teach for instance in col. 1, lines 33-40, that "the detection and/or quantitation of specific nucleic acid sequences is an increasingly important technique for identifying and classifying microorganisms, diagnosing infectious diseases, detecting and characterizing genetic abnormalities, identifying genetic changes associated with cancer, studying genetic susceptibility to disease, and measuring response to various types of treatment." Such motivation suggests detection of chromosomal abnormalities in a sample as claimed.

Rowley et al. and the remaining references were incorporated to teach motivation in the art to detect certain specific gene translocations claimed in the dependent claims.

Although other similar inventions may also be suggested by the combination of the recited art (as applicant points out on page 12 of the response), the combination of the above references reads on the claims as broadly claimed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

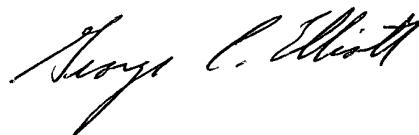
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

M. M. Schmidt  
April 10, 2000



George C. Elliott, Ph.D.  
Supervisory Patent Examiner  
Technology Center 1600